

REMARKS

Claims 1-4 and 7-23 remain pending.

Claim Rejections – 35 USC § 112

Claims 1-4 and 7-23 are rejected under 35 USC § 112 as being indefinite because claims 1 and 16 are unclear as to how the position sensing system registers instantaneous position readings in contrast to fixed readings of the static positions, and as to how the central point is determined from the pattern formed by the plurality of static positions.

The Applicants respectfully submit that a person skilled in the art to which the application relates would on the contrary clearly grasp the subject matter of claims 1 and 16 and understand the differences in registering what are known as instantaneous position readings versus readings of static positions. The Applicants also point to paragraphs 21 and 22 of the description, where it is stated that, for instantaneous position readings, “the surgeon stays in a static position for a minimum amount of time while the system registers a plurality of readings. The position is then determined by taking an average of all of the instantaneous positions that are within a certain range.” Alternatively, for a static position reading, “the surgeon places the bone in a static position and enables the system to register the position.” Since such nomenclature is already understood by a person skilled in the art and is further detailed in the description, the Applicants believe that the language in the claims is clear. Reconsideration of the rejection is kindly requested.

As for the central point, it is known that the movement of the femur with respect to the pelvis is orbital with respect to a center, namely the center of the femoral head in the acetabulum of the pelvis. Therefore, from the “pattern formed by said plurality of static positions”, a person skilled in the art would know how to calculate the central point (i.e., the center of the femoral head). Reconsideration of the rejection is kindly requested.

Claim Rejections – 35 USC § 103

Claims 1-4 and 7-23 are rejected under 35 USC § 103 as being obvious over Carson et al. (US2003/0069591) in view of Dance et al. (U.S. 5,611,353) or Leitner (WO 02/47559).

The Applicants respectfully traverse the rejections in view of the following reasons.

Claim 1 recites: "displaying said mechanical axis on an output device without reference to an image of said femur acquired pre-operatively or intra-operatively using a medical imaging device".

The Applicants agree with the Examiner's position that Carson et al. manifestly departs from using imageless systems and therefore does not teach "displaying said mechanical axis on an output device without reference to an image of said femur acquired pre-operatively or intra-operatively using a medical imaging device" as claimed with respect to claim 1.

In addition, the Applicants believe that a person skilled in the art would not have arrived at the claimed subject matter from a combination of Dance et al. or Leitner to Carson et al. A combination of those teachings does not lead a person skilled in the art to achieve the claimed subject matter for the following reasons:

With respect to Carson et al., it is clear that the reference teaches away from performing any kind of modifications to the method disclosed in order to eliminate the use of imaging devices for pre-operatively or intra-operatively acquiring an image of a femur. Carson et al. specifically suggest the use of a medical imaging device to obtain images of appropriate body parts. This is shown, for example, in paragraph [0008], paragraph [010] and paragraph [0013]. Carson clearly teaches against the use of imageless systems again in paragraph [0019] by stating in reference to "imageless" systems that "This can be very time intensive resulting in longer operating room time. (...) This is also problematic in patients with a pathologic condition. (...) These systems are also much slower, almost doubling operating room time and expense." From this evidence, it is clear that the reference teaches away from the subject matter as recited in claims 1 and 16.

With respect to Dance et al., all of the figures, including Figures 4, 5a to 5c, show the display of information with an image of a femur. The figures therefore suggest displaying the axis with reference to an image of the femur acquired pre-operatively or intra-operatively. The description also does not support the contrary. In col. 5, line 64 to col. 6, line 6, it is stated: "At this point the position of second location marker 42 is measured and digitized by camera array 38 and object digitizing and display equipment 54 permitting ankle joint center 16 to be located with respect hip joint center 14 locating the patient's weight bearing axis with respect to registration clamp 30 and the distal landmarks on femur 10 used to position registration clamp 30. This information can then be displayed by object digitizing and display equipment 54 and used by the surgeon to guide resurfacing cuts on femur 10 and tibia 12" (emphasis added). Dance et al. teaches that information can be displayed but does not show that it is conventional in the art to display a "mechanical axis on an output device without reference to an image of the femur acquired pre-operatively or intra-operatively using a medical imaging device" as claimed.

In respect to Leitner, the Applicants point out that the abstract does not teach a method which displays a "mechanical axis on an output device without reference to an image of the femur acquired pre-operatively or intra-operatively using a medical imaging device" as claimed. Leitner discloses calculating "the position of the mechanical axis of the femur (...) from the various position data of the femur in various positions. The aim of the invention is to avoid using a marking element on the pelvic bone. To this end, the femur is pivoted from a starting position in various directions at only a maximum pivoting angle of 15 DEG (...)" Nothing in the abstract therefore suggests the claimed subject matter. Moreover, the figures in Leitner fail to show navigated bones on screen.

For the above reasons, a person skilled in the art would not have arrived at the subject matter claimed in claim 1 from a combination of Carson et al. with Leitner or Dance et al., as all references fail to describe the concept of displaying axes pertaining to bone elements without reference to bone images.

For similar reasons, a person skilled in the art would not have arrived at the subject matter claimed in claim 16, which recites: "wherein said mechanical axis is determined and

displayed on said output device without reference to an image of said femur acquired pre-operatively or intra-operatively using a medical imaging device".

The rejections of claims 1 and 16, as well as the rejections of dependent claims 2-4, 7-15 and 17-23 under 35 USC § 103, are thus moot.

In addition to the above, and in regard to claims 4 and 11, the Applicants further point out that, as stated by the Examiner, Dance et al. and Leitner do not disclose expressly that the "pattern formed by the plurality of static positions is a conical pattern" as claimed in claim 4, nor do they disclose "moving the proximal end at least 20 mm to a next static position" as claimed in claim 11.

The Applicants point out that paragraph [020] of the application supports the above stated and claimed subject matter of claims 4 and 11 as providing an advantage and thus having a particular purpose, that is, to provide better results. The Applicants stress the importance of judicious positioning of the leg at each step of the method.

The Applicants also submit that this positioning would not have been *prima facie* obvious to a person skilled in the art in view of Carson et al., Leitner or Dance et al. None of the prior art suggests such movements of the leg.

Dance et al. teaches "Following a minimum of three different measurements, object digitizing and display equipment 54 calculates the position of joint hip center 14 using the constraints that each measured point lies on the surface of a sphere centered at joint hip center 14 and that hip joint center 14 lies proximal to the attachment point of registration clamp 30" (emphasis added). Dance et al. simply teaches three different measurements. Dance et al. does not suggest positioning the femur as claimed in claims 4 and 11.

Leitner teaches that "the position of the mechanical axis of the femur is calculated in relation to the same from the various position data of the femur in various positions" (emphasis added). "(...) the femur is pivoted from a starting position in various directions at only a maximum pivoting angle of 15 DEG and the mechanical axis of the femur is calculated from the position data of the surface marked by the marking element and from the position data of the

knee joint determined elsewhere." Nothing in Leitner suggests positioning the femur as claimed in claims 4 and 11.

For the above reasons, the Applicants find the rejections to claims 4 and 11 under 35 USC § 103 moot.

In view of the above remarks, this application is believed to be in condition for allowance and early notice to that effect is earnestly solicited.

Respectfully submitted,

ALAIN RICHARD ET AL.

By:

Pierre TIA-NGUYEN (Reg. No. 55,043)
Agent of Record
OGILVY RENAULT LLP
1981 McGill College Avenue, Suite 1600
Montreal, Quebec, Canada H3A 2Y3
Tel.: (514)847-4243